

# "Ask me about the HPV vaccine"

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#### **DISCLOSURE:**

Dr. Humiston's institution (CMH) receives funding from "Pfizer Independent Grants for Learning & Change" for her work to develop and test a curriculum to teach residents about how to manage vaccine hesitancy. This relationship is not relevant to this presentation.

Dr. Humiston's participation today was funded by a grant from CDC to APA.

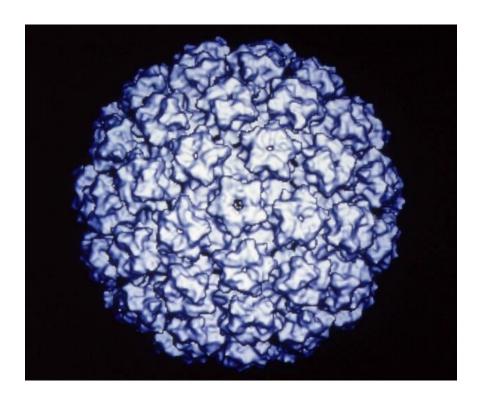


### The learner should be able to:

- 1. Describe the importance of HPV vaccination.
- 2. Implement the same way, same day approach to HPV vaccination for 11- & 12-yr-olds
- 3. Demonstrate the ability to answer parents' FAQs accurately and succinctly.
- 4. Name 3 ways to increase HPV vaccination rates in a primary care office

#### **Objective #1**

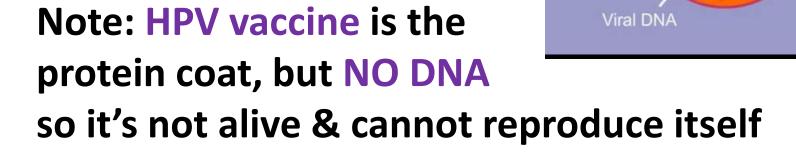
# THE IMPORTANCE OF HPV VACCINATION



## **Human Papillomavirus (HPV)**

#### 2 components:

- L1 protein coat –
- Double stranded DNA



For more details, see You Tube animated videos:

https://www.youtube.com/watch?v=WSL8rBMWW1Y

https://www.youtube.com/watch?v=L7g2LfDwYc8 (from NCI)

In most cases, cells infected with HPV heal on their own.

However, in some cases HPV infection leads to **transformation of cells** from healthy to cancerous.

# How does HPV infection cause cancer?



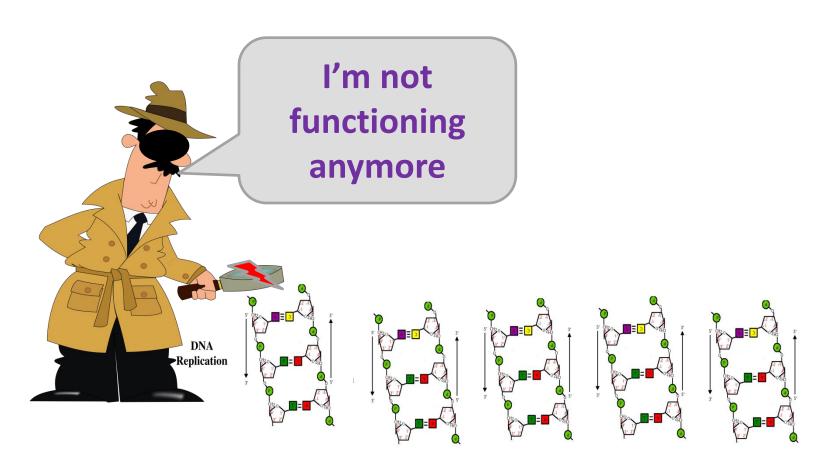
Scans the cell's DNA for mutations

Replication

Stops cells from dividing if there's a DNA mutation

During an HPV infection, the virus can integrate some of it's DNA into the human cell's DNA.

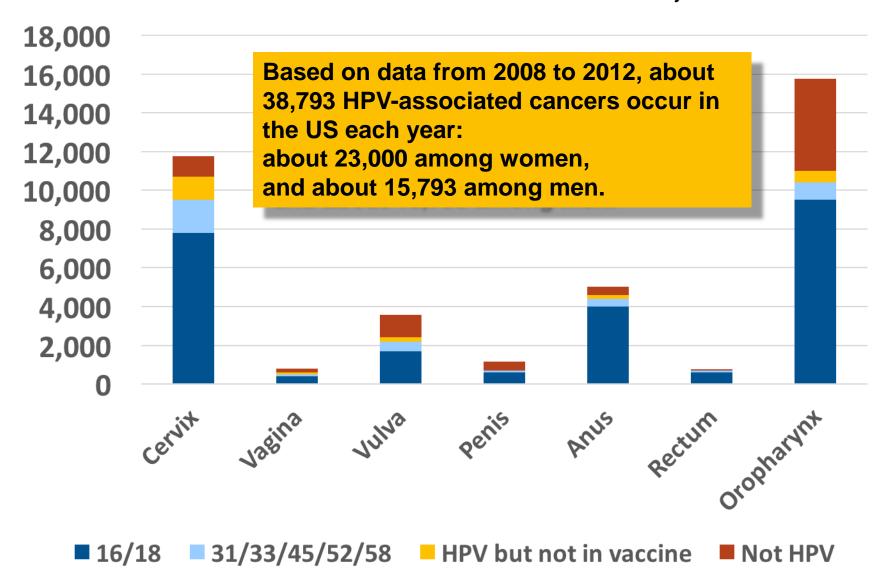
Then the human cell's genome itself starts producing a protein that <u>inhibits</u> its tumor suppressor protein!



Without functioning tumor suppressor protein, a human cell may continue to replicate its DNA even if that DNA is mutated.

Uncontrolled replication leads to cancer.

# Average number of cancers per year in sites where HPV is often found, US



## Where is the oropharynx?

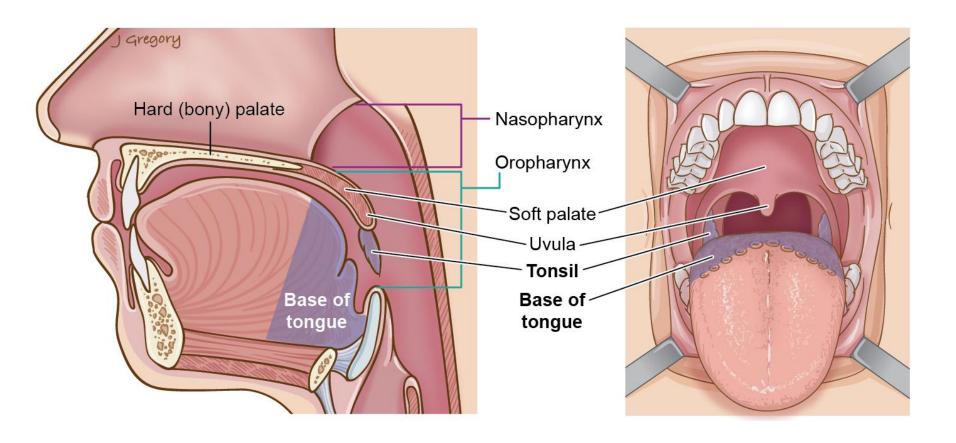
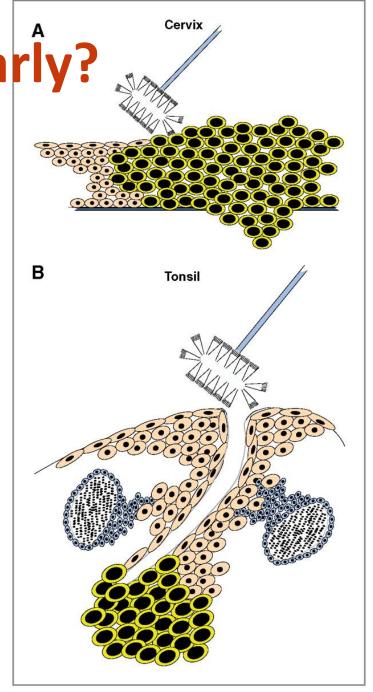


Image Source: American Cancer Society

Catching OP Cancer Early?

Symptoms commonly mis-interpreted

- Location
  - Back of the throat
  - Deep in crypts



### Side effects of non-surgical therapy

Side Effect	Percent affected
Taste Disturbance	88%
Nausea/Vomiting	36%
Dry Mouth	29-38%
Esophageal Stricture	5%
Require G tube > 1 year	9%



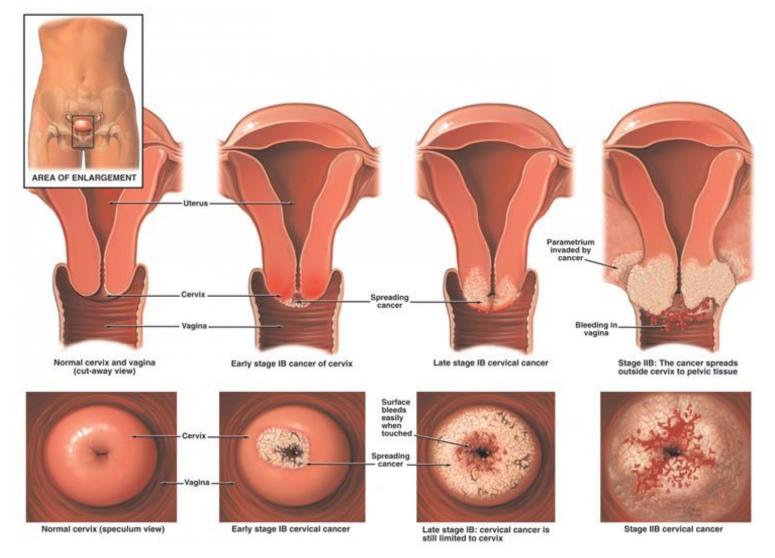
Irune, et al, 2014; Kocak-Uzel, et al, 2014; Nutting, et al, 2011; McBride, et al, 2014

Photo credit: http://www.jpalliativecare.com/viewimage.asp?img=IndianJPalliatCare 2010 16 2 74 68408 f3.jpg

## **Oropharyngeal Cancer Survivor**



### **Cervical Cancer & Pre-cancers**

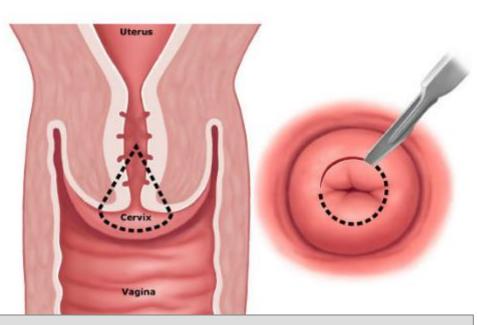


# Even pre-cancerous lesions have implications for a woman and her offspring.

New cases of cervical dysplasia each year in the US:

■1.4 million low grade

**■**330,000 high grade



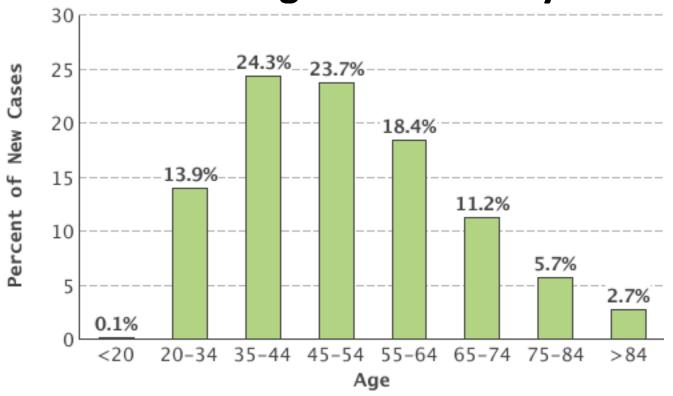
Loop electrosurgical excision procedure (LEEP) or a cold-knife cone biopsy

### **LEEP and Cone Biopsy**

- May be used to treat moderate to severe types of abnormal cell changes (CIN II or CIN III) or even <u>very</u> early stage cervical cancer
- Subsequent pregnancies are at risk of
  - Perinatal mortality
  - Preterm delivery
  - Low birth weight

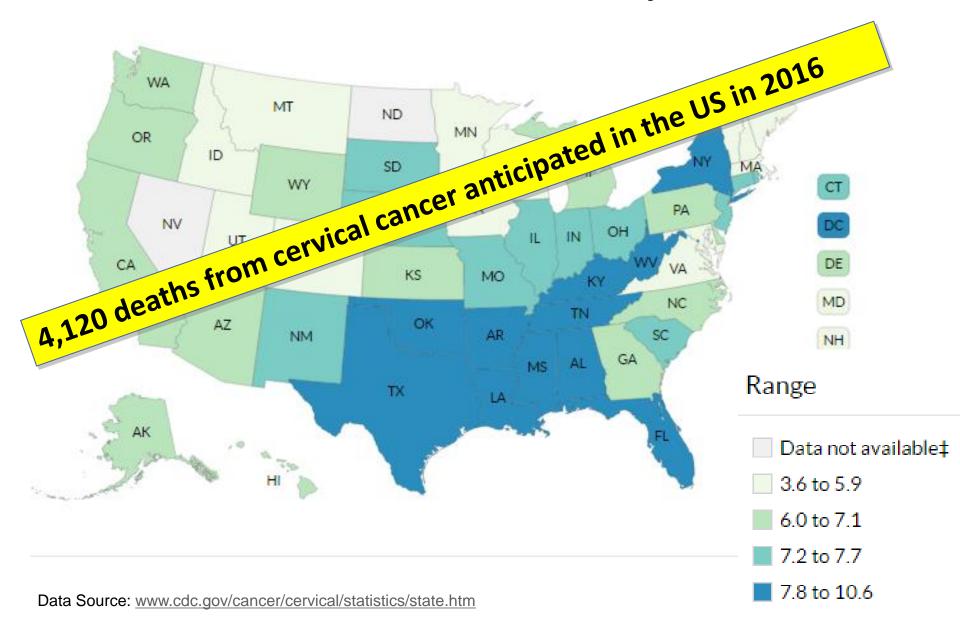
### **Cervical Cancer During Child-bearing Years**

# 38% of cervical cancers occur in women between the ages of 20 & 44 years.



http://seer.cancer.gov/statfacts/html/cervix.html

#### **Cervical Cancer Incidence Rates by State, 2013**



#### State-based disparities in

#### **HPV-associated oropharyngeal cancer**



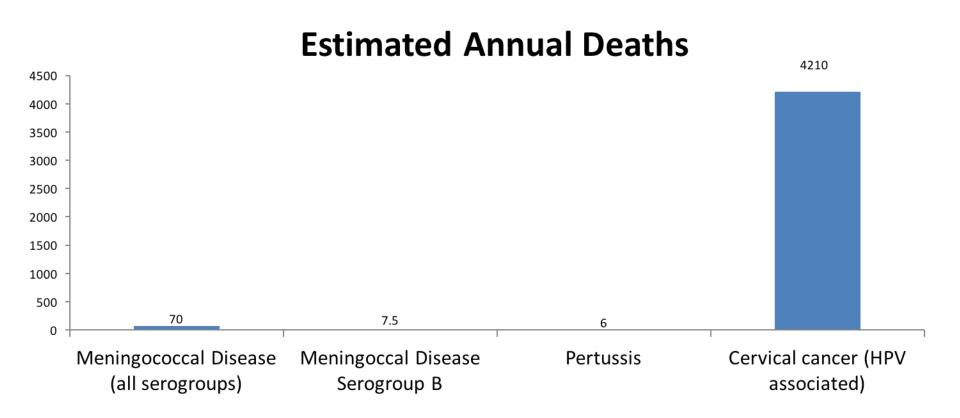


#### Women



Data Source: Adapted from www.cdc.gov/cancer/hpv/statistics/state/oropharyngeal.htm

## Deaths from Diseases Covered in Adolescent Vaccine Series

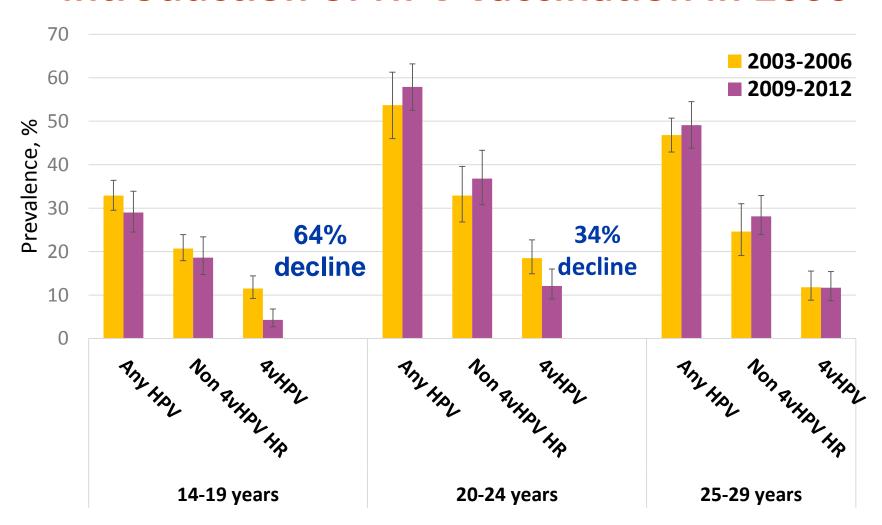


Data Sources: CDC, 2016; CDC 2015; American Cancer Society

# THE IMPORTANCE OF HPV VACCINATION?

Is prevents infection with HPV types that cause cancer and pre-cancers

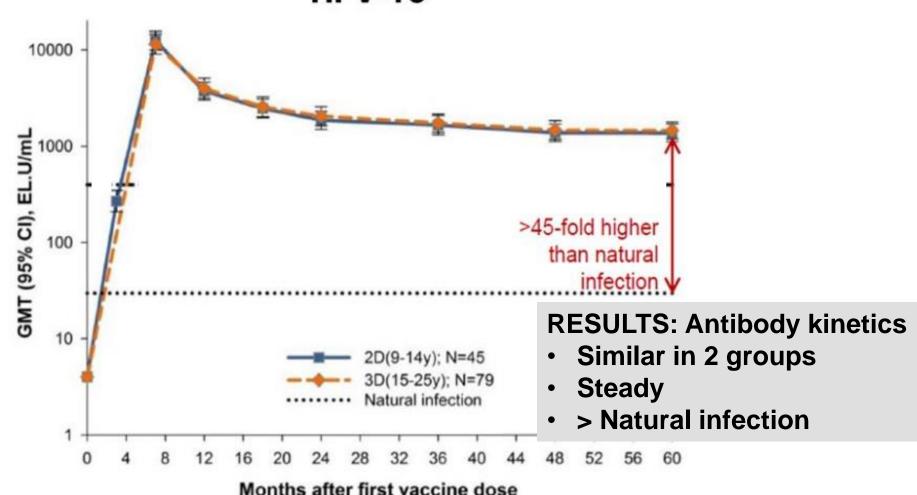
# Prevalence of HPV before & after US introduction of HPV vaccination in 2006



http://pediatrics.aappublications.org/content/early/2016/02/19/peds.2015-1968

## **Does immunity last?**

Follow-up through month 60 HPV-16



Data Source: Adopted from Romanowski, 2016

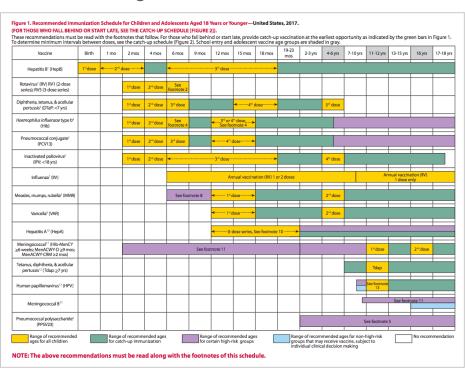
Antibody measured by ELISA

## Evidence of lasting immunity

- For 2 or 3-dose schedule?
  - No evidence of waning protection after a 3-dose schedule
  - So far, antibody persistence for 2-dose schedule appears similar to 3-dose schedules
- How long?
  - Data available through ~ 10 years for 2vHPV and 4vHPV
  - Longer follow-up, through 14 years, ongoing in some studies

### **2017 Immunization Schedule**

www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

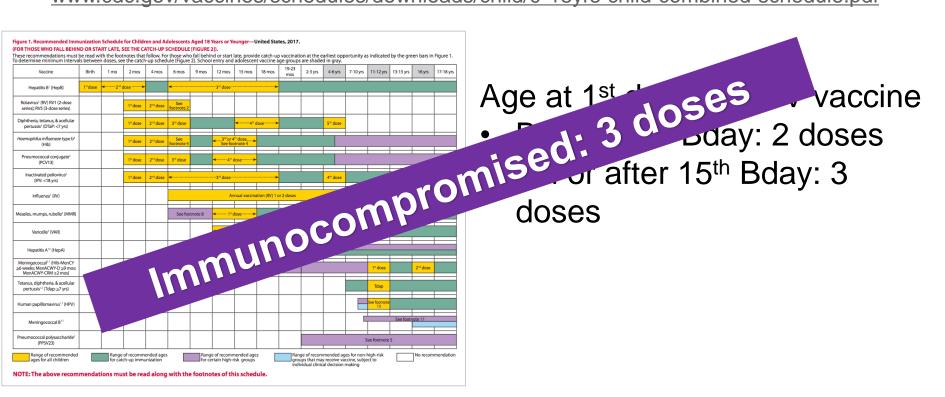


Age at 1<sup>st</sup> dose of HPV vaccine

- Before 15<sup>th</sup> Bday: 2 doses
- On or after 15<sup>th</sup> Bday: 3 doses

### 2017 Immunization Schedule

www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf



# What forms of "immunocompromise" necessitate a 3-dose HPV vaccine series?

Needs 3 doses irrespective of age: Primary or secondary conditions that might reduce cell-mediated or humoral immunity

#### **Examples:**

- B lymphocyte Ab deficiencies
- T lymphocyte complete or partial defects
- HIV infections
- Malignant neoplasm
- Transplantation
- Autoimmune disease
- Immunosuppressive therapy

Can use 2 dose series for those initiating before 15<sup>th</sup> birthday:

- Asthma
- Asplenia
- Diabetes mellitus
- Sickle cell disease
- Chronic granulomatous disease
- Chronic disease of liver, lung, kidneys
- Heart disease
- CNS barrier defects (eg, cochlear implant)
- Complement deficiency, persistent complement component deficiency

# Recommended # of Doses & Dosing Schedule for HPV Vaccine

Population	Rec. # of doses	Rec. dosing schedule	Minimum intervals
Started series at ages 9 through 14 years, except immunocompromised persons	2	0, 6–12 mos	5 mos between doses
Started series at ages 15 through 26 years, and immunocompromised persons (any age)	3	0, 1–2, 6 mos	4 weeks btwn doses 1-2 12 weeks btwn doses 2-3 5 mos btwn doses 1-3

## Case example - 1

A boy is starting the HPV vaccine series on his 15<sup>th</sup> birthday.

How many doses does he need in total?

A. 0

B. 2

C. 3

This adolescent needs 3 doses (0, 1-2, 6 months schedule) because he is starting the series on (or after) the 15<sup>th</sup> birthday.



## Case example - 2

A 13 year old has a history of 2 doses of HPV vaccine:

4vHPV given at age 12 years and 9vHPV given 6 months later. How many more doses are needed?

- A. 0
- B. 1
- C. 2

No further doses are recommended because she initiated vaccination before the 15<sup>th</sup> birthday and received 2 doses of vaccine 6 months apart.



### Case example - 3

A 13 year old has a history of 2 doses of HPV vaccine:

4vHPV given at age 11 years & 9vHPV given 2 months later.

How many more doses are needed?

A. 0

B. 1

C. 2

1 more dose...

Although she initiated the vaccination series before her 15<sup>th</sup> birthday, she needs another dose because HPV vaccine doses #1 and #2 were administered <5 months apart.

Give a 3rd dose with a minimum of 12 weeks between doses 2-3 and a minimum of 5 months between doses 1-3

### **Interrupted Vaccination Schedules**

If the vaccination schedule is interrupted, the vaccination series does not need to be restarted.

# http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/age-interval-table.pdf

Recommended and Minimum Ages and Intervals Between Doses of Routinely Recommended Vaccines 1,2,3,4							
Vaccine and dose number	Recommended age for this dose	Minimum age for this dose	Recommended interval to next dose	Minimum interval to next dose			
Diphtheria-tetanus-acellular pertussis (DTaP)-15	2 months	6 weeks	8 weeks	4 weeks			
DTaP-2	4 months	10 weeks	8 weeks	4 weeks			
DTaP-3	6 months	14 weeks	6-12 months	6 months <sup>6</sup>			
DTaP-4 <sup>6</sup>	15-18 months	12 months <sup>6</sup>	3 years	6 months			
DTaP-5	4-6 years	4 years	_	_			
Haemophilus influenzae type b (Hib)-15.7	2 months	6 weeks	8 weeks	4 weeks			
Hib-2	4 months	10 weeks	8 weeks	4 weeks			
Hib-3 <sup>8</sup>	6 months	14 weeks	6-9 months	8 weeks			
Hib-4	12-15 months	12 months	_	_			
Hepatitis A (HepA)-15	12-23 months	12 months	6-18 months	6 months			
HepA-2	≥18 months	18 months	_	_			
Hepatitis B (HepB)-15	Birth	Birth	4 weeks-4 months	4 weeks			
HepB-2	1-2 months	4 weeks	8 weeks-17 months	8 weeks			
HepB-3 <sup>9</sup>	6-18 months	24 weeks	_	_			
Herpes zoster (HZV) <sup>10</sup>	≥60 years	60 years	_	_			
Human papillomavirus (HPV)-1 <sup>11</sup>	11-12 years	9 years	8 weeks	4 weeks			
HPV-2	11-12 years (+ 2 months)	9 years (+ 4 weeks)	4 months	12 weeks <sup>12</sup>			
HPV-3 <sup>12</sup>	11-12 years (+ 6 months)	9 years (+24 weeks)	_	_			
Influenza, inactivated (IIV) <sup>13</sup>	≥6 months	6 months <sup>14</sup>	4 weeks	4 weeks			

# RECOMMEND HPV VACCINE THE "SAME WAY, SAME DAY"

# When is a recommendation not a recommendation?

- "I vaccinate whenever a parent requests HPV vaccine."
- "I just can't bring myself to talk about the possibility that this child will have sex when she's an 11-year old."
- To parent: "Today we have 3 vaccines for your child: Tdap which is required for school, MCV which is required for a lot of colleges, and HPV which is optional."

# Recommend HPV vaccine the <u>same day</u> & the <u>same way</u> as other adolescent immunizations

Same day: Recommend HPV vaccine today, i.e., the same day you recommend Tdap & meningococcal vaccines.

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More convenient for the parent More reliable

# Recommend HPV vaccine the <u>same day</u> & the <u>same way</u> as other adolescent immunizations

Same day: Recommend HPV vaccine today, i.e., the same day you recommend Tdap & meningococcal vaccines.

Same way: Bundle all the ROUTINELY RECOMMENDED adolescent vaccines and recommend them all in the same way with the assumption that the parent will want protection for their child.

Today, Pat should have 3 shots that will protect her from a form of meningitis, some cancers caused by HPV, and whooping cough.

What questions do you have for me?

### If a parent hesitates...

#### The MA/nurse should say ...

"Our team is so dedicated to cancer prevention. I'm sure the doctor will want to respond to your concerns."

# If a parent has a question...

#### Don't panic!

My 2 knee jerk rxns:

- Feel like we're heading into time-sucking conflict
- Feel like my authority's being challenged

Interpret a question as a request for reassurance from YOU, a clinician they trust

### Case example: The hesitant parent

- An 11 year old girl comes to your office for well-care.
- You offer a 'presumptive' recommendation for the vaccines, saying "Great, you're here for your vaccines. We can go ahead and do her tetanus/diphtheria/whooping cough vaccine, her HPV vaccine, and her meningitis vaccine."

Not so fast. The mother says:

"We're okay doing that tetanus shot and the meningitis one, but we're going to hold off on the HPV vaccine."

#### How to Handle Resistance:

#1: Ask the parent to share her/his concern(s)

#### **Example:**

"So you seem to have concerns about the HPV vaccine. Well, that's perfectly understandable – I've had a number of questions about this one. Would you mind sharing what your particular concerns are?" (Note: non-threatening)

"Well, I've heard that it's a vaccine to prevent a disease that's transmitted by having sex, and she is a looooong way from having sex."

### How to Handle Resistance: #2 – Reflect, summarize, ask, advise

The provider reflects back what the parent is saying to be sure he/she understands (empathy) and summarizes what has been heard before proceeding, again with permission, to make a recommendation.

#### **Example:**

"So I can hear that you're concerned that she's too young for the HPV vaccine because HPV is transmitted by sexual activity. Well, I completely get that — she's only 11 after all. I've thought a lot about this. Is it okay if I go over how I've come to think about this vaccine?"

# How to Handle Resistance: #3 – The crucial step

#### **Example:**

What NOT to say: "Well, data shows that many adolescents will be having sex by middle school, and if you're worried about her having sex, studies have shown that it won't increase the likelihood of her having sex."

# How to Handle Resistance: #3 – The crucial step

#### **Example:**

What TO say: "I used to think of this vaccine as something to prevent a sexually transmitted disease, but I've realized it's really about preventing cancer. Almost everyone gets this virus, so I think it's important for everyone."

# How to Handle Resistance: #4 – Make a personalized recommendation

#### **Example:**

"If she were my daughter I wouldn't hesitate to recommend this vaccine for her, and most of my patients now are getting the vaccine.

Having said that, this is a decision that only you and your daughter can make. What do you think?"

### Summary: How to Handle Resistance

- Engage the parent & patient respectfully and fully in the discussion
- Use empathy, collaboration, evocation and support for autonomy
- Use open-ended questions and reflections
- Use behavior change principles-emphasizing social norms, pivoting from debunking the myth that she is too young, and focusing on the disease that is prevented rather than negatives (eg, side effects)
- Make a clear, strong, & personalized recommendation

# A small percentage of parents will decline or delay



### If a parent declines...

- Declination is not final.
   The conversation can be revisited.
   Declining = Delaying
- End the conversation with <u>at least 1 action</u> you both agree on.
- Because waiting to vaccinate is the risky choice, many pediatricians ask the parent to sign a *Declination Form*

Re	efusal to	Vaccinate
Child's Name		
My child's doctor/nurse,		countries and that my unvaccinated child could easily get one of these diseases while traveling or from a traveler.
Recommended	Declined	<ul> <li>If my child does not receive the vaccine(s) according to the medically accepted schedule, the consequences may include</li> </ul>
☐ Hepatitis B vaccine		<ul> <li>Contracting the illness the vaccine is designed to prevent</li> </ul>
Diphtheria, tetanus, acellular pertussis (DTaP or Tdap) vaccine		(the outcomes of these illnesses may include one or more of the following: certain types of cancer, pneumonia, illness
Diphtheria tetanus (DT or Td) vaccine		requiring hospitalization, death, brain damage, paralysis, meningitis, seizures, and deafness; other severe and
☐ Hoemophilus influerase type b (Hib) vaccine		permanent effects from these vaccine-preventable
☐ Pneumococcal conjugate or polysaccharide vaccine		diseases are possible as well).
☐ Inactivated policylrus (IPV) vaccine		<ul> <li>Transmitting the disease to others (including those too young to be vaccinated or those with immune problems).</li> </ul>
Measles-mumps-rubella (MMII) vaccine		possibly requiring my child to stay out of child care or school
☐ Varicella (chickenpox) vaccine		and requiring someone to miss work to stay home with my
☐ Influenza (flu) vaccine		child during disease outbreaks.
☐ Meningococcal conjugate or polysaccharide vaccine		<ul> <li>My child's doctor and the American Academy of Pediatrics, the American Academy of Family Physicians, and the Centers</li> </ul>
☐ Hepatitis A vaccine		for Disease Control and Prevention all strongly recommend
☐ Rotavirus vaccine		that the vaccine(s) be given according to recommendations.
Human papillomavirus (HPV) vaccine		Nevertheless, I have decided at this time to decline or defer the vaccine(s) recommended for my child, as indicated above, by check

# https://www2.aap.org/immunization/pediatricians/pdf/refusaltovaccinate.pdf

mended vaccine(s). A list of reasons for vaccinating, possible health consequences of non-vaccination, and possible side effects of each vaccine is available at www.oc.gov/vaccines/pubs/vis/default.htm. I understand the following:

- The purpose of and the need for the recommended vaccine(s).
- The risks and benefits of the recommended vaccine(s).

nurse at any time and that I may change my mind and accept vaccination for my child any time in the future.

I acknowledge that I have read this document in its entirety and fully understand it.

Parent/Guardian Signature:	Date:
Witness	Date:
I have had the opportunity to rediscuss my decision not to v	accinate my child and still decline the recommended immunizations.

American Academy of Pediatrics

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# ANSWER FREQUENTLY ASKED QUESTIONS FROM PARENTS & OTHER CLINICIANS

# Addressing Parents' Top Questions about HPV VACCINE

Parents may be interested in vaccinating, yet still have questions. Some parents might just need additional information from you, the clinician they trust.

Taking the time to answer their questions and address their concerns can help parents to accept a recommendation for HPV vaccination.

WHEN PARENTS SAY: Why does my child need the HPV vaccine?	TRY SAYING:  HPV vaccine is important because it prevents cancer. That is why I recommend that your daughter/son be vaccinated today.
What diseases are caused by HPV?	Certain HPV types can cause cancer of the cervix, vagina, and vulva in females, cancer of the penis in men, and in both females and males, cancers of the anus and the throat. We can help prevent infection with the HPV types that cause these cancers by starting the HPV vaccine series for your child today.
Is my child really at risk for HPV?	HPV is a very common and widespread virus that infects both females and males. We can help protect your child from the cancers and diseases caused by the virus by starting HPV vaccination today.
Why do they need HPV vaccine at such a young age?	HPV vaccination works best at the recommended ages of 11 or 12 years.
I have some concerns about the safety of the vaccine—I keep reading things online that says	I know there are stories in the media and online about vaccines, and I can see how that could concern you. However, I want you to know that HPV vaccine has been carefully studied for many years by medical and

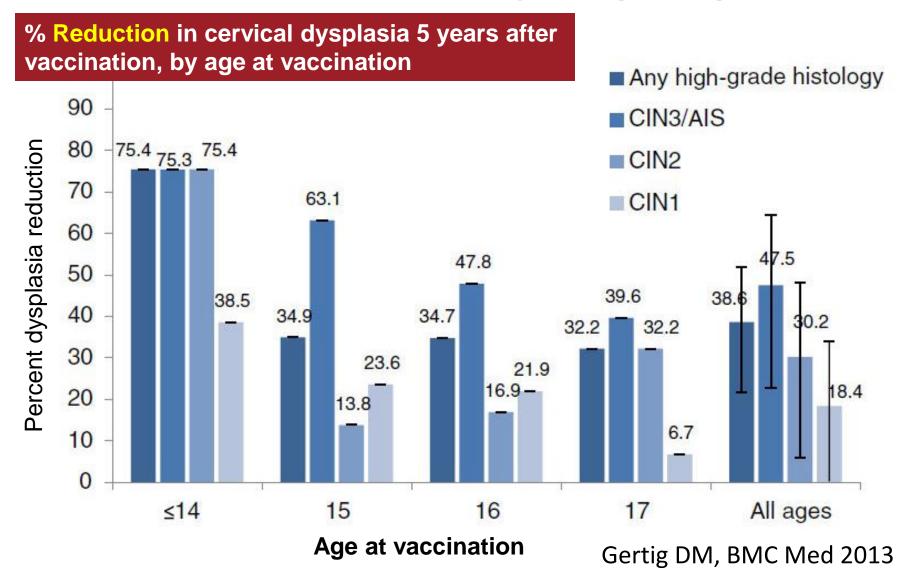
http://www.cdc.gov/vaccines/who/teens/for-hcp-tipsheet-hpv.pdf

# Why give HPV vaccine at 11-12 years of age rather than later?

- 2 doses instead of 3 if started before 15<sup>th</sup> bday
- Long-lasting protection
- Optimal vaccine efficacy if the vaccine series is completed before onset of sexual activity

http://pediatrics.aappublications.org/content/129/3/602.full

# Higher effectiveness with vaccination at younger ages



# "Profiling" does not work.

Do I really want to bet your patient's life on *guessing* right?



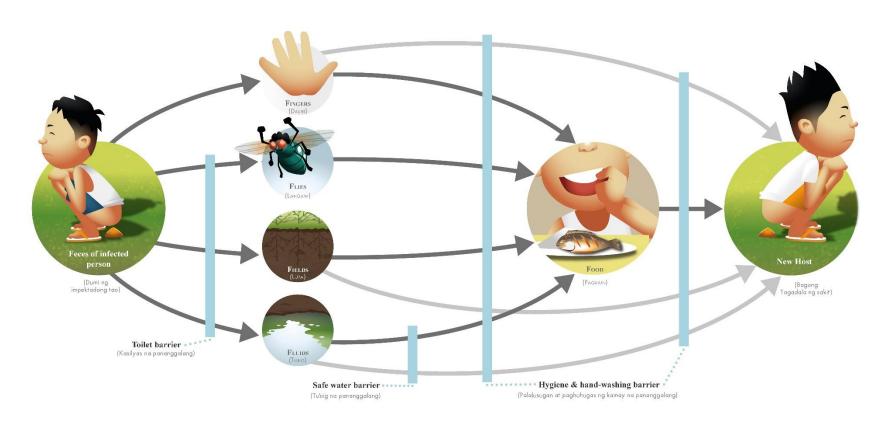
# Marriage is not an anti-viral.



A newlywed can catch HPV from her/his spouse.

### "I don't want to talk about sex."

### "I don't want to talk about sex."



# Did you explain fecal-oral spread before you gave the polio vaccine?

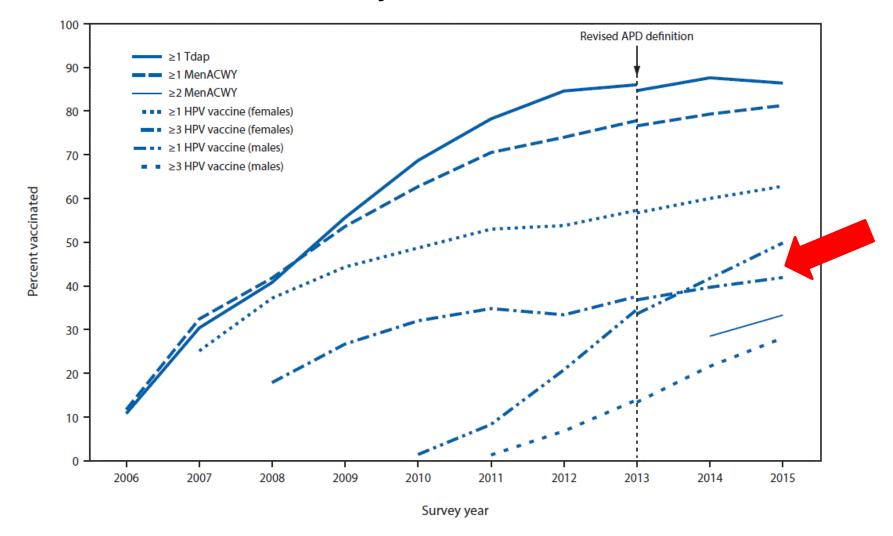
### "Is HPV vaccine safe?"

# Studies on Gardasil (vs unvaccinated) have shown that vaccinated females are <u>not</u> more likely to develop:

- 2011- allergic reactions, anaphylaxis, Guillain-Barré
   Syndrome, stroke, blood clots, appendicitis, or seizures
   (than unvaccinated or who received other vaccines)
- □ 2013 (almost 1 million girls) blood clots or AEs related to the immune & CNS
- □ 2014 (>1 million women) venous thromboembolism or blood clots
- □ 2012 and 2014 (2 studies) autoimmune disorders
- □ 2015 MS or similar diseases
- 2012 vaccine may be associated with skin infections where the shot is given during the two weeks after vaccination and fainting on the day the shot is received

# INCREASE HPV VACCINATION RATES IN A PRIMARY CARE OFFICE

# Estimated vaccination coverage with selected vaccines and doses among adolescents aged 13–17 years, by survey year - National Immunization Survey-Teen, US, 2006–2015

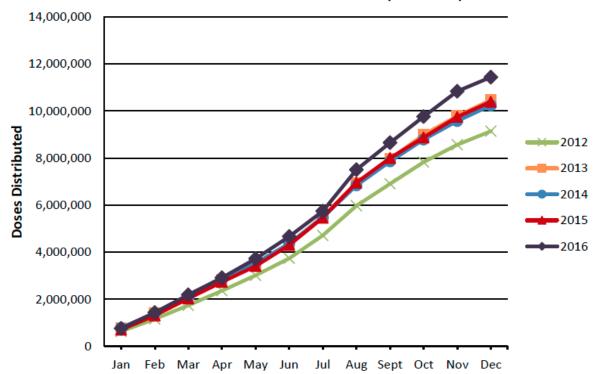


# Estimated vaccination coverage among adolescents aged 13–17 years, by state— National Immunization Survey-Teen (NIS-Teen), US, 2015

			FEMALES Only HPV Doses			MALES Only HPV Doses		
	Tdap	MenACWY	≥1	≥2	≥3	≥1	≥2	≥3
US	86.4	81.3	62.8	52.2	41.9	49.8	39.0	28.1
IA	85.5	75.0	66.7	62.3	49.8	48.0	37.0	23.9
KS	87.3	63.7	50.9	43.6	31.7	36.0	26.3	18.5
МО	85.7	69.7	59.3	43.4	31.5	44.7	33.7	25.1
NE	87.7	78.1	67.3	55.5	48.2	54.3	46.9	32.2

### # of Doses Distributed

#### Year-to-date Total of Distributed<sup>†</sup> 4-valent HPV vaccine and 9-valent HPV vaccine Doses in the United States (2012-2016)



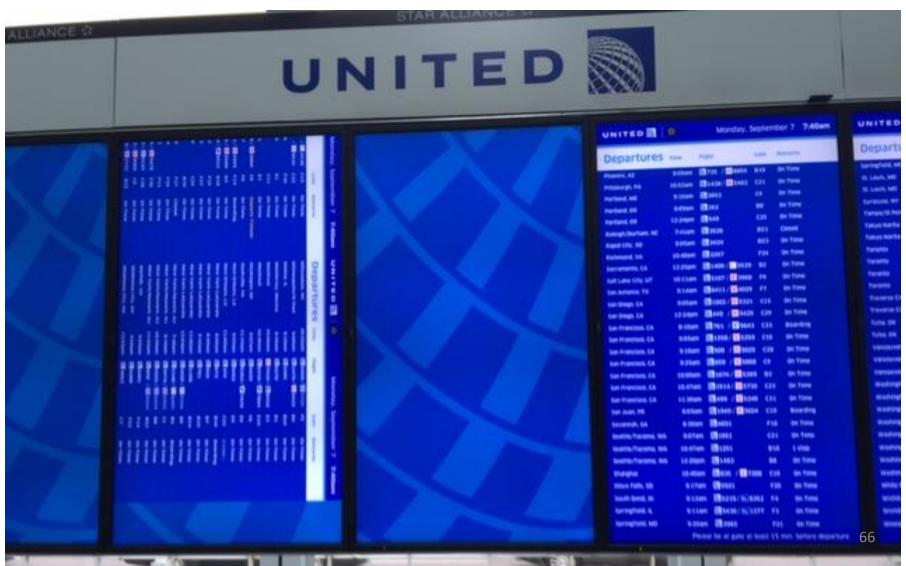
Note: Cervarix doses, which represent less than 1% of the HPV vaccine doses distributed in the United States, are not included in this report.

#### Year-to-Date Total of Distributed<sup>†</sup> 4-Valent and 9-Valent HPV Vaccine, US (2015-2016)

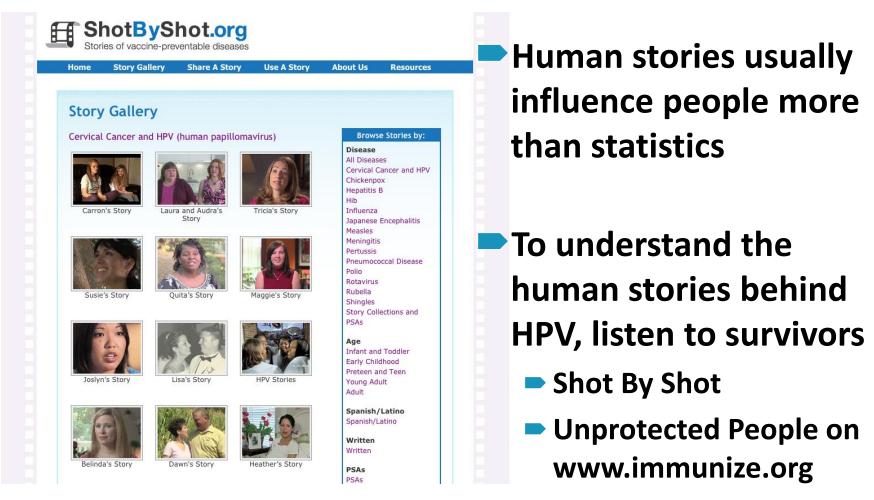
	2015	2016	% change	
Jan	704,540	758,591	7.7%	
Feb	1,309,896	1,435,056	9.6%	
Mar	2,028,793	2,184,949	7.7%	
Apr	2,730,981	2,911,014	6.6%	
May	3,405,341	3,722,032	9.3%	
Jun	4,302,453	4,661,314	8.3%	
Jul	5,455,515	5,745,014	5.3%	
Aug	6,954,029	7,502,757	7.9%	
Sept	7,997,691	8,648,293	8.1%	
Oct	8,873,834	9,756,923	10.0%	
Nov	9,744,100	10,832,569	11.2%	
Dec	10,389,014	11,434,759	10.1%	

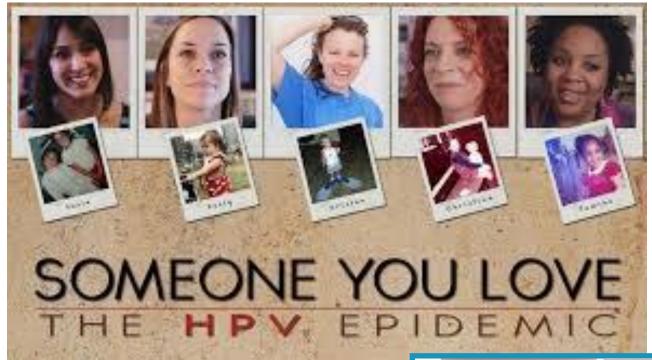
<sup>†</sup>These data represent an estimate of all Gardasil and Gardasil 9 HPV vaccine doses distributed in the United States.

# Every part of your practice influences parents' perceptions



# Create Immunization Champions Be sure everyone in the office understands the mission





http://www.hpvepidemic.com/



### How to improve: 2 Approaches

### Increase the # of target patients who:

#### 1. Come in

- Reminder/recall
- Office hours
- Nurse only visits to complete series

#### Leave the office vaccinated

- Use every visit
- Use provider prompts
- Use standing orders

For more information, including free resources for yourself and your patients/clients, visit: cdc.gov/vaccines/YouAreTheKey

Email questions or comments to CDC Vaccines for Preteens and Teens:

PreteenVaccines@cdc.gov

### **For More Information**

Shot by Shot
 http://shotbyshot.org/story-gallery

AAP

Info for parents (healthychildren.org)
Info for clinicians (http://www2.aap.org/
immunization/illnesses/hpv/hpv.html)

- Immunization Action Coalition http://www.immunize.org/
- CHOP Vaccine Education Center <a href="http://vec.chop.edu/">http://vec.chop.edu/</a>
- EZ IZ
   http://eziz.org/
- American Cancer Society



### Review

- 1. The importance of HPV vaccination.
- 2. The same way, same day approach to HPV vaccination for 11- & 12-yr-olds
- 3. Answer parents' FAQs accurately and succinctly.
- 4. Increase HPV vaccination rates in a primary care office